(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 959 757 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
06.05.2004 Bulletin 2004/19

(21) Application number: **97935031.1**

(22) Date of filing: **21.07.1997**

(51) Int Cl.[7]: **A61B 5/00**, A61B 5/024

(86) International application number:
PCT/US1997/012715

(87) International publication number:
WO 1998/005252 (12.02.1998 Gazette 1998/06)

(54) INFANT/NEONATAL PULSE OXIMETER SENSOR

PULSE OXIMETERFÜHLER FÜR NEUGEBORENE

SPHYGMO-OXYMETRE NEONATAL OU POUR NOURRISSONS

(84) Designated Contracting States:
DE FR GB

(30) Priority: **07.08.1996 US 695243**

(43) Date of publication of application:
01.12.1999 Bulletin 1999/48

(73) Proprietor: **Nellcor Puritan Bennett Incorporated**
Pleasanton, CA 94588 (US)

(72) Inventor: **MANNHEIMER, Paul, D.**
Danville, CA 94506 (US)

(74) Representative: **Belcher, Simon James**
Urquhart-Dykes & Lord
Tower North Central
Merrion Way
Leeds LS2 8PA (GB)

(56) References cited:
EP-A- 0 572 684
EP-A- 0.641 543
WO-A-96/15714
DE-C- 4 429 845

EP 0 959 757 B1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to oximeter sensors, and in particular to pulse oximeter sensors for use on an infant's foot.

[0002] Pulse oximetry is typically used to measure various blood flow characteristics including, but not limited to, the blood-oxygen saturation of hemoglobin in arterial blood, the volume of individual blood pulsations supplying the tissue, and the rate of blood pulsations corresponding to each heartbeat of a patient. Measurement of these characteristics has been accomplished by use of a non-invasive sensor which scatters light through a portion of the patient's tissue where blood perfuses the tissue, and photoelectrically senses the absorption of light in such tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

[0003] The light scattered through the tissue is selected to be of one or more wavelengths that are absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of transmitted light scattered through the tissue will vary in accordance with the changing amount of blood constituent in the tissue and the related light absorption. For measuring blood oxygen level, such sensors have typically been provided with a light source that is adapted to generate light of at least two different wavelengths, and with photodetectors sensitive to both of those wavelengths, in accordance with known techniques for measuring blood oxygen saturation.

[0004] Known non-invasive sensors include devices that are secured to a portion of the body, such as a finger, an ear or the scalp. In animals and humans, the tissue of these body portions is perfused with blood and the tissue surface is readily accessible to the sensor.

[0005] Pulse oximetry is used on infants and neonates in the NICU, and increasingly at home, for detection of hypoxemia. In the home, it is believed that early detection of hypoxic events may be a more reliable indicator and warning for the onset of Sudden Infant Death, and related disorders, than the currently used apnea monitors. Pulse oximetry sensors require attachment to the hand, foot, toe or finger (transmission sensors), or to a flat surface (reflectance sensors) where there is good perfusion of blood within the tissue. On small infants and neonates, the conventional approach is to tape the pulse oximetry sensor in place on the foot. For the home care market, this becomes an inconvenience as the sensor must be applied each and every time the baby is not being watched by the parents or other care provider. Repeatedly applying and removing the taped-on sensor is considered irritating to the skin of the baby, and leads to non-compliance by the parents. Additionally, adhesive sensors are generally single-use or limited re-use, adding a substantial expense to the cost of home monitoring. Clip-on sensors offer an alternative, but tend to fall off as well as being more motion sensitive.

[0006] A pulse oximeter sensor is typically applied across the top and bottom of the middle of an infant's foot. In one study, the pulse oximeter sensor was applied across the back of the foot above the heel at the achilles tendon ("Clinical Investigation, Evaluation of Oxygen Saturation Monitoring by Pulse Oximetry in Neonates in the Delivery System," Ivan Dimich et al., Canadian Journal of Anaesthesia, 1991, 38:8, pp 985-988).

[0007] EP 0 641 543 discloses a pulse oximeter comprising a light emitting diode and detector which can be positioned on opposite sides of the instep of a foot and secured by means of an adhesive.

SUMMARY OF THE INVENTION

[0008] The present invention provides an improved infant/neonatal pulse oximeter sensor which will attach to an infant's foot in an improved manner. Strong adhesives are not required, although a light adhesive or gel may be used to improve the conformance of the sensor of the invention. The invention preferably provides a pad which conforms or is conformable to the shape of the infant or neonate's foot, although a non-conforming pad or cup may also be used.

[0009] The pad conforms to the heel of the infant, with the emitter and detector preferably being mounted below the achilles tendon and below the calcaneus bone. The heel pad can be held in place with a stretchable sock.

[0010] In an alternate embodiment, the conformable pad is a sock with pockets cut in it for holding the emitter and detector. A nylon mesh or other semi-transparent material forms the inside of the pockets, allowing light to escape the emitter and be detected by the detector.

[0011] Preferably, the cabling attached to the emitter and detector extends up the infant's heel a short distance to a connector which can be subsequently connected to a separate cable attached to a pulse oximeter monitor. The short cabling attached to the sensor provides more ease of attachment to an infant.

[0012] Additionally, the emitter and detector are preferably insertable into the pockets or depressions in the pad, thus making the emitter and detector reusable while the pad or sock can be disposable.

[0013] For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014]

Fig. 1 is a diagram of one embodiment of heel pad

sensor according to the present invention applied to an infant's foot;

Fig. 2 is a diagram showing an inside view of the sensor of Fig. 1;

Fig. 3 is a diagram of an infant's foot showing the location of the calcaneus bone;

Fig. 4 is a diagram of a "Y-sensor" for use with a disposable pad for attaching to an infant's foot according to one embodiment of the invention;

Figs. 5 and 6 are disassembled and assembled diagrams, respectively, of one embodiment of a heel pad according to the present invention;

Fig. 7 is a diagram of an alternate embodiment of a sock-type pad according to the present invention; and

Figs. 8A-11B are diagrams illustrating different emitter and detector locations on a patient's heel.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0015] Fig. 1 illustrates one embodiment of a sensor pad 10 attached to a foot 12 of an infant. Pad 10 conforms to the heel of the infant foot 12, and includes a light emitter 14 on one side, and a detector on the other side (not shown in Fig. 1). A cable 16 providing connections to the emitter and detector is connected to a connector 18. By keeping this cable short, the infant will not get wrapped up with it upon application of the pad, and it can be subsequently attached to another connector for a cable connected to a pulse oximeter monitor.

[0016] Fig. 1 also shows an optional ECG sensor 13, which would have a separate conductor in cable 16. In addition, an additional sensor 15 may be used, and may be a reflectance sensor. Additional sensor 15 may be a complete sensor, or just a detector which shares emitter 14. Alternately, a single detector could share two emitters. In such a reflectance sensor, the emitter and detector can be located on the side of the heel as shown in Fig. 1, or both components can be located on the bottom of the heel pad. Alternatively, one component may be on the side and one may be on the bottom.

[0017] Fig. 2 illustrates pad 10 of Fig. 1 before application to the infant's foot. The view of Fig. 2 shows the inside of the heel pad cup. An emitter 14 and a detector 20 are shown. The emitter and detector can be separated sufficiently for a transmittance mode of operation, or can be placed closer together, or on the same side of the heel or on the bottom of the heel, for a reflectance mode of operation. The pad itself can be cut from flat material, which can be folded and glued along lines 22, 24, or molded to the proper shape. The pad could be made of a number of materials, such as foam, rubber or thermoplastic. Alternately, the pad may be constructed by laminating multiple layers together, sandwiching the optical components and wires internally. The pad is preferably held onto the heel by a stretchable sock, such as lycra or nylon, but may also be held in place with straps fabricated from a variety of materials such as Velcro. The sock should be of sufficient tightness to hold the heel pad to the heel without allowing it to move, but not so tight as to constrict blood flow.

[0018] Fig. 2 also shows a raised portion 25 which can serve as a shunt barrier. This will prevent light from shunting from the emitter to the detector without going through the infant's skin. The shunt barrier ridge 25 will abut up against the infant's heel even if the remainder does not, thus blocking a path for light around the end of the infant's heel.

[0019] Fig. 3 shows a cutaway rear view of an infant's heel. Preferably, the emitter and detector are mounted below the calcaneus bone 26, as shown in Fig. 3. This region is well perfused with blood and allows sufficient light transmission for the oximeter to function properly.

[0020] An additional advantage of placing a sensor on the heel is that an infant's heel size changes little as it grows from a birth weight (approximately 3.18kg (7 pounds)) up to around 10kg (22 pounds). By contrast, the bridge of the foot will increase size more dramatically.

[0021] The inventor also recognized that the heel provides a good registration position for a sensor, as opposed to other locations where it might be difficult to secure the sensor in the desired location. The use of a stretchable sock to hold the heel pad in place also can be advantageous in constricting the foot slightly, keeping venous blood out and thus reducing undesired artifacts in the detected signal and enhancing arterial pulse amplitude.

[0022] In one embodiment, the heel pad is reusable, with openings in the pad for holding the emitter 14 and detector 20. Fig. 4 illustrates a "Y-sensor" having a separate emitter 14 and detector 20. These are mounted in plastic housings which have protrusions on the backside, with protrusion 28 being visible in the view shown. These protrusions can be inserted into correspondingly shaped recesses in the heel pad to secure the emitter and detector in place. The entire housing could also be placed in recesses having shapes conforming to those of the emitter and detector housings. Two cables 30 and 32 are joined by member 34, and thereafter a single cable assembly 16 is used. In this way, the separate portions don't extend very far, avoiding entanglement. Cables 30 and 32 can be fabricated from wires or by using flexible circuits.

[0023] Figs. 5 and 6 show an alternate embodiment of a heel pad. Fig. 5 illustrates a resilient material 36 with cutout windows 38 and 40 for the detector and emitter. Edges 42 and 44 can be glued together to form a heel cup as shown in Fig. 6. Fig 6 shows the assembled heel cup pad 36 with cable 16 attached. In the assembled form, a rounded opening 46 provides for registration with the bottom of an infant's heel, and also allows the cup to accommodate heels of different size since different amounts of the heel will extend through the opening 46. Window 38 is shown in the view of Fig. 6, while window 40 is obscured. A front portion 50 of the

pad is designed to slide slightly under the infant's heel when engaged.

[0024] Heel pad 36 could be made of a number of different materials, such as molded foam, rubber or thermoplastic. In particular, Neoprene™ rubber could be used, or a foam such Poron™ or Urethane™. Another possible material would be Santoprene™. Preferably, the material would have good memory, that is, it would retain its shape conformable to the foot even after being distorted by manipulation. Alternately, the heel pad may be constructed as a lamination of two or more layers of tapes, in a construction similar to the Nellcor N-25 Oxisensor. The heel pad may be conforming to the infant's foot, either as a hard, molded shape or as a pliable, conformable shape that can be distorted. Preferably, the heel pad is constructed with materials and configuration in such a manner so as to minimize optical interference from ambient light sources.

[0025] The emitter and detector can be flush in a recess in the heel pad, or alternately can be recessed to provide a specified air gap. The specified air gap could eliminate variations in the light path where, in response to motion, the emitter and detector are alternately in direct contact with the skin, and then have an air gap. By ensuring that there is always an air gap, the variations would be much less in the detected light due to motion. Alternately, the emitter and detector can be flush with the infant's foot.

[0026] Fig. 7 shows an alternate embodiment of the invention in which a special sock 52 is used having a pocket 54 on top of the foot, and a pocket 56 on the bottom of the foot. The emitter and detector can be inserted into the pockets and connected to cable 16. The inside of the pocket has a mesh 58 facing the infant's foot, which may be a nylon mesh, for instance. Alternately, a transparent plastic or other material may be used. The mesh or transparent material must be sufficiently strong to hold the sensor in place in the pocket and sufficiently transparent to allow light to pass through it. An optional securing strap 60, such as a Velcro™ strap, is used to hold cable 16 in place, and prevent motion of the cable further away from the emitter and detector from moving the emitter and detector in the pockets. Pockets 56 and 58 could also be located across the heel pad below the Calcaneus as is practiced in Fig. 1. Alternately, a sock with recesses or holes for holding the emitter and detector could be used, without any covering between the emitter and detector and the patient's foot.

[0027] Figs. 8-11 show alternate locations for the placement of an emitter and detector according to the present invention. Fig. 8A is a bottom view, and Fig. 8B is a side view, illustrating the emitter and detector being on the side of a foot adjacent a heel of a patient. Figs. 9A and 9B illustrate bottom and side views, respectively, of the emitter and detector being adjacent each other along the bottom of the heel, aligned side-by-side. Figs. 11A and 11B illustrate a view of the emitter and detector aligned along the bottom of a heel on a line extending from the front to back of a foot. Figs. 10A and 10B illustrate the detector being on the bottom of the heel, while the emitter is on the side. Alternately, these positions can be reversed, or any other combination of the positions set forth in Figs. 8-11 could be used.

[0028] Constituents other than arterial blood oxygen saturation may be determined, such as glucose, blood gases, or blood flow characteristics. Furthermore, optical fibers or optical fiber bundles may be used to couple one or both the light source and light detector to the substrate, with the electro-optic emitter and/or detection placed in a remote location.

Claims

1. An optical method for determination of a blood characteristic comprising the steps of:

   securing an emitter (14) and detector (20) to a patient;
   emitting electromagnetic radiation with the emitter (14);
   detecting the electromagnetic radiation with the detector (20) and producing a signal; and
   determining a blood characteristic in the patient from the detector signal; **characterised in that** the emitter (14) and detector (20) are coupled to a substrate which has a shape similar to that of a heel such that the emitter and detector can be applied to spaced-apart positions on the heel (12).

2. The method of claim 1 wherein said securing step includes placing a sock (52) over said emitter (14) and detector (20).

3. The method of claim 1 wherein said securing step includes attaching said emitter (14) and detector (20) to a sock (52).

4. The method of claim 1 further comprising the step of detecting transmitted light with said detector (20).

5. The method of claim 1 further comprising the step of detecting reflected light with said detector (20).

6. The method of claim 1 wherein said blood characteristic is oxygen saturation.

7. The method of claim 1 wherein said steps are applied to a patient weighing less than 15kg.

8. An oximeter sensor comprising:

   an emitter (14) coupled to a non-adhesive substrate (10, 36); and

a detector (20) coupled to the substrate (10, 36) a distance from the emitter (14); **characterised in that** the substrate (10, 36) has a shape similar to that of a heel (12) of a patient.

9. The sensor of claim 8 further comprising a sock (52) for holding said substrate (10, 36) against said patient's foot.

10. The sensor of claim 8 further comprising at least one strap (60) for holding said substrate (10, 36) against said patient's foot.

11. The sensor of claim 8 wherein said substrate comprises a sock (52), said sock including:

a first pocket (54) for securing said emitter, said first pocket including a substantially transparent material between said emitter and said patient; and
a second pocket (56) for securing said detector, said second pocket including a substantially transparent material between said emitter and detector.

12. The sensor of claim 8 wherein at least one of said emitter (14) and detector (20) is on one of a side, bottom and rear of said foot.

13. The sensor of claim 8 wherein at least one of said emitter (14) and detector (20) is recessed in said substrate (36) to form an air gap between said one of said emitter and detector and said foot.

14. The sensor of claim 8 wherein said substrate is resilient (10, 36) and has a shape conformable to a heel of a patient, and wherein said emitter (14) and detector (20) are mounted in said resilient substrate to engage an infant patient's heel (12) below the calcaneus bone (26).

15. The sensor of claim 8 wherein said substrate comprises a sock (52), said sock including cavities (54, 56) for holding said emitter and said detector.

16. The sensor of claim 8 wherein further comprising an ECG sensor mounted in said substrate.

17. The sensor of claim 8 wherein further comprising a second oximeter sensor mounted in said substrate.

Patentansprüche

1. Optisches Verfahren zur Ermittlung eines Blut-Charakteristikums, welches die folgenden Schritte umfasst:

Befestigung einer Strahlungsquelle (14) und eines Detektors (20) an einem Patienten;

Aussenden elektromagnetischer Strahlung durch die Strahlungsquelle (14);

Detektieren der elektromagnetischen Strahlung mit dem Detektor (20) und Erzeugung eines Signals; und

Bestimmung eines Blut-Charakteristikums innerhalb des Patienten aus dem Detektor-Signal;

dadurch gekennzeichnet, daß
die Strahlungsquelle (14) und der Detektor (20) mit einem Trägermaterial verbunden sind, welches eine Form ähnlich derjenigen einer Ferse hat, so daß die Strahlungsquelle und der Detektor in voneinander beabstandeten Positionen an der Ferse (12) anbringbar sind.

2. Verfahren nach Anspruch 1, bei dem der BefestigungsSchritt das Überziehen eines Strumpfes (52) über die Strahlungsquelle (14) und den Detektor (20) umfasst.

3. Verfahren nach Anspruch 1, bei dem der BefestigungsSchritt das Anbringen der Strahlungsquelle (14) und des Detektors (20) an einem Strumpf (52) umfasst.

4. Verfahren nach Anspruch 1, welches außerdem den Schritt umfasst, durchgelassenes Licht mit dem Detektor (20) zu detektieren.

5. Verfahren nach Anspruch 1, welches außerdem den Schritt umfasst, reflektiertes Licht mit dem Detektor (20) zu detektieren.

6. Verfahren nach Anspruch 1, bei dem das Blut-Charakteristikum die Sauerstoff-Sättigung ist.

7. Verfahren nach Anspruch 1, bei dem die Schritte bei einem Patienten angewendet werden, welcher weniger als 15 kg wiegt.

8. Oximeter-Fühler, welcher umfasst:

eine Strahlungsquelle (14), welche mit einem nicht klebenden Trägermaterial (10, 36) verbunden ist; und

einen Detektor (20), welcher in einem Abstand zu der Strahlungsquelle (14) mit dem Trägermaterial (10, 36) verbunden ist;

dadurch gekennzeichnet, daß

das Trägermaterial (10, 36) eine Form aufweist, welche ähnlich derjenigen einer Ferse (12) eines Patienten ist.

9. Fühler nach Anspruch 8, welcher außerdem einen Strumpf (52) aufweist, um das Trägermaterial (10, 36) an dem Fuß eines Patienten anliegend zu halten.

10. Fühler nach Anspruch 8, welcher außerdem wenigstens eine Befestigungsschelle (60) aufweist, um das Trägermaterial (10, 36) an dem Fuß des Patienten anliegend zu halten.

11. Fühler nach Anspruch 8, wobei das Trägermaterial einen Strumpf (52) umfasst, und der Strumpf aufweist:

eine erste Tasche (54), um die Strahlungsquelle zu befestigen, wobei die erste Tasche ein im wesentlichen transparentes Material zwischen der Strahlungsquelle und dem Patienten aufweist; und

eine zweite Tasche (56), um den Detektor zu befestigen, wobei die zweite Tasche ein im wesentlichen transparentes Material zwischen der Strahlungsquelle und dem Detektor aufweist.

12. Fühler nach Anspruch 8, wobei wenigstens entweder die Strahlungsquelle (14) oder der Detektor (20) auf der Seite, der Unterseite oder der Rückseite des Fußes angeordnet ist.

13. Fühler nach Anspruch 8, wobei wenigstens entweder die Strahlungsquelle (14) oder der Detektor (20) derart in das Trägermaterial (36) eingelassen ist, daß sich ein Luftspalt zwischen entweder der Strahlungsquelle oder dem Detektor und dem Fuß bildet.

14. Fühler nach Anspruch 8, wobei das Trägermaterial elastisch (10, 36) ist und eine Form aufweist, welche an eine Ferse eines Patienten anpaßbar ist, und wobei die Strahlungsquelle (14) und der Detektor (20) derart in dem elastischen Trägermaterial befestigt sind, daß sie in die Ferse (12) eines Kleinkind-Patienten unterhalb des Calcaneus-Knochens (26) eingreifen.

15. Fühler nach Anspruch 8, wobei das Trägermaterial einen Strumpf (52) umfasst und der Strumpf Hohlräume (54, 56) aufweist, um die Strahlungsquelle und den Detektor zu halten.

16. Fühler nach Anspruch 8, welcher außerdem einen EKG-Fühler aufweist, der in dem Trägermaterial befestigt ist.

17. Fühler nach Anspruch 8, welcher außerdem einen zweiten Oximeter-Fühler aufweist, der in dem Trägermaterial befestigt ist.

Revendications

1. Procédé optique pour la détermination d'une caractéristique sanguine, comprenant les étapes suivantes :

- la fixation d'un émetteur (14) et d'un détecteur (20) sur un patient ;
- l'émission d'un rayonnement électromagnétique à l'aide de l'émetteur (14) ;
- la détection du rayonnement électromagnétique à l'aide du détecteur (20) et la production d'un signal ; et
- la détermination d'une caractéristique du sang du patient à partir du signal du détecteur ;

caractérisé en ce que l'émetteur (14) et le détecteur (20) sont couplés à un substrat possédant une forme similaire à celle d'un talon de telle façon que l'émetteur et le détecteur puissent être appliqués sur des positions espacées sur le talon (12).

2. Procédé selon la revendication 1, selon lequel ladite étape de fixation comprend le placement d'une chaussette (52) sur lesdits émetteur (14) et détecteur (20).

3. Procédé selon la revendication 1, selon lequel ladite étape de fixation comprend la fixation desdits émetteur (14) et détecteur (20) sur une chaussette (52).

4. Procédé selon la revendication 1, comprenant, de plus, une étape de détection de la lumière transmise à l'aide dudit détecteur (20).

5. Procédé selon la revendication 1, comprenant, de plus, une étape de détection de la lumière réfléchie à l'aide dudit détecteur (20).

6. Procédé selon la revendication 1, selon lequel ladite caractéristique sanguine est une saturation en oxygène.

7. Procédé selon la revendication 1, selon lequel lesdites étapes sont appliquées à un patient pesant moins de 15 kg.

8. Capteur oxymétrique, comprenant :

- un émetteur (14) couplé à un substrat non adhésif (10, 36) ; et

- un détecteur (20) couplé au substrat (10, 36) à une certaine distance de l'émetteur (14) ;

caractérisé en ce que le substrat (10, 36) présente une forme similaire à celle du talon (12) d'un patient.

9. Capteur selon la revendication 8, comprenant, de plus, une chaussette (52) pour maintenir ledit substrat (10, 36) contre le pied dudit patient.

10. Capteur selon la revendication 8, comprenant, de plus, au moins une bande (60) pour maintenir ledit substrat (10, 36) contre le pied dudit patient.

11. Capteur selon la revendication 8, dans lequel ledit substrat comprend une chaussette (52), ladite chaussette comprenant :

- une première poche (54) pour la fixation dudit émetteur, ladite première poche comprenant un matériau sensiblement transparent interposé entre ledit émetteur et ledit patient ; et
- une seconde poche (56) pour fixer ledit détecteur, ladite seconde poche comprenant un matériau sensiblement transparent interposé entre ledit émetteur et ledit détecteur.

12. Capteur selon la revendication 8, dans lequel au moins un desdits émetteur (14) et détecteur (20) se trouve sur un des côtés latéraux, du bas et arrière dudit pied.

13. Capteur selon la revendication 8, dans lequel au moins un desdits émetteur (14) et détecteur (20) est logé en creux dans ledit substrat (36) afin de former un intervalle d'air entre ledit moyen parmi lesdits émetteur et détecteur et ledit pied.

14. Capteur selon la revendication 8, dans lequel ledit substrat est élastique (10, 36) et possède une forme s'adaptant au talon d'un patient et dans lequel lesdits émetteur (14) et détecteur (20) sont montés dans ledit substrat élastique afin d'engager le talon d'un enfant (12) en dessous du calcanéum (26).

15. Capteur selon la revendication 8, dans lequel ledit substrat comprend une chaussette (52), ladite chaussette comprenant des cavités (54, 56) pour contenir ledit émetteur et ledit détecteur.

16. Capteur selon la revendication 8, comprenant, de plus, un capteur ECG monté dans ledit substrat.

17. Capteur selon la revendication 8, comprenant, de plus, un second capteur oxymétrique monté dans ledit substrat.

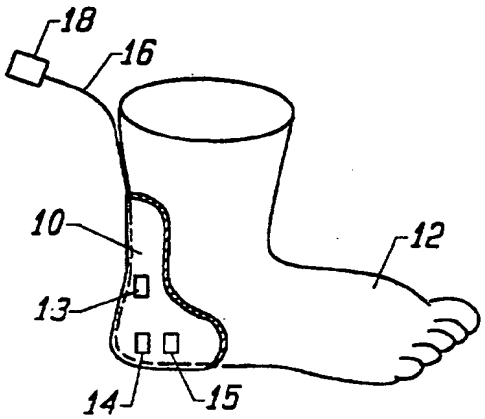

FIG. 1

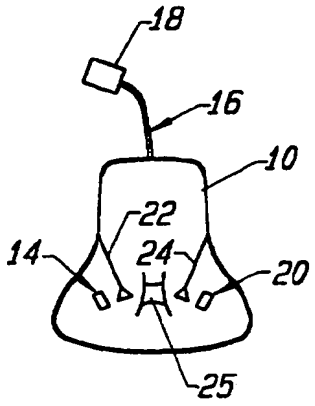

FIG. 2

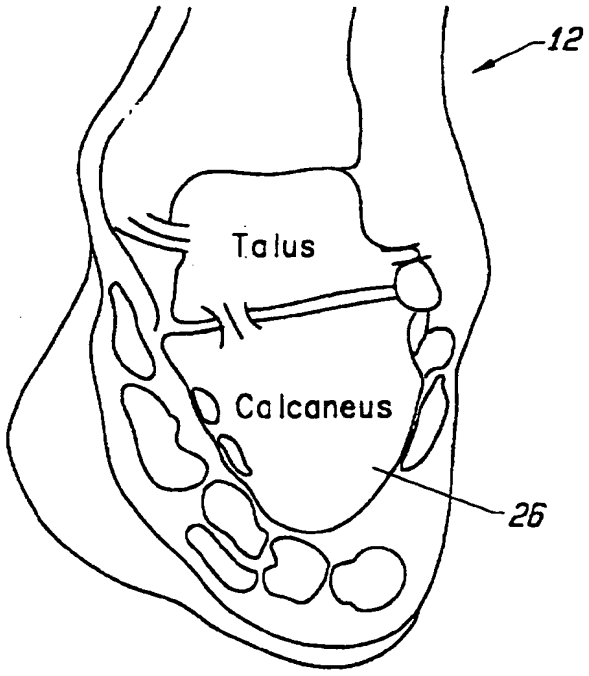

FIG. 3

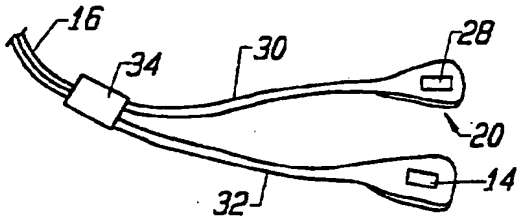

FIG. 4

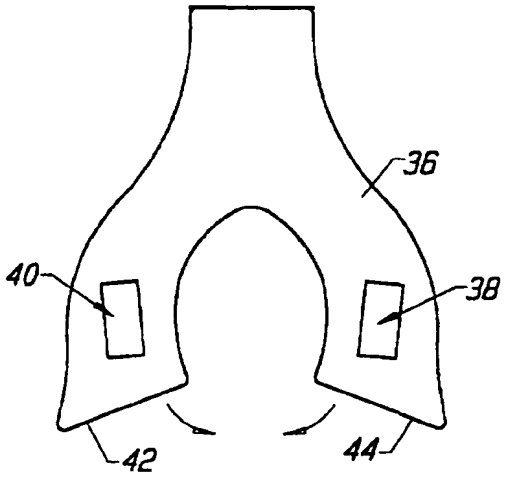

FIG. 5

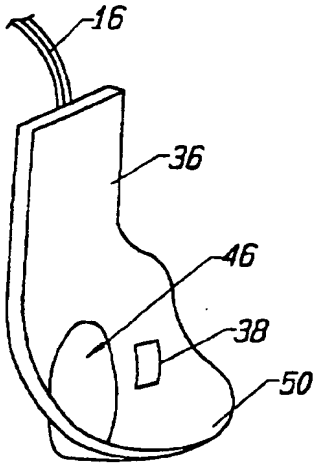

FIG. 6

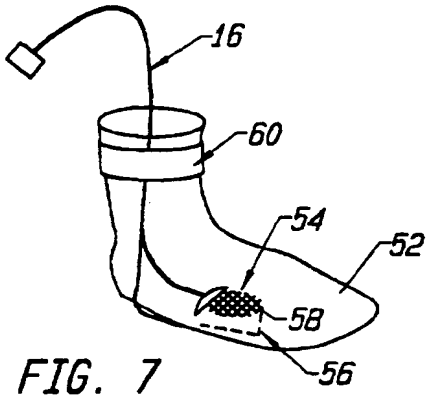

FIG. 7

FIG. 8A

FIG. 8B

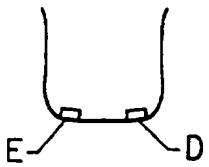

FIG. 9A

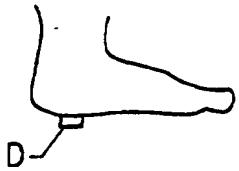

FIG. 9B

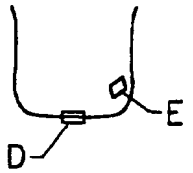

FIG. 10A

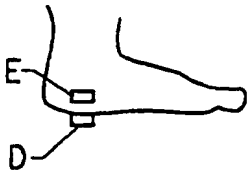

FIG. 10B

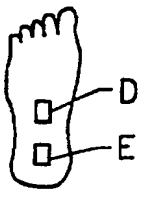

FIG. 11A

FIG. 11B